

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS**

PUBLIC HEALTH AND MEDICAL) PROFESSIONALS FOR) TRANSPARENCY,)) Plaintiff,)) v.) Civil Action No. 4:21-cv-01058-P) UNITED STATES FOOD AND DRUG) ADMINISTRATION,)) Defendant.))
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ANSWER TO PLAINTIFF'S COMPLAINT

Defendant, the U.S. Food and Drug Administration (“FDA”) by and through undersigned counsel, hereby answers the Complaint (ECF No. 1) (“Complaint”) filed by Plaintiff Public Health and Medical Professionals for Transparency (“PHMPT”) on September 16, 2021, as follows, in correspondingly numbered paragraphs:

1. Admitted that until August 23, 2021, all vaccines legally available to the public for the prevention of COVID-19 in the United States were authorized by FDA under emergency use authorization. Except as so expressly admitted, the allegations of paragraph 1 are denied.
2. Admitted.
3. The allegations in first two lines of this paragraph purport to characterize a news release by FDA, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the news release, the first two lines of this paragraph are denied. The rest of the paragraph consists of Plaintiff's characterization of alleged “questions” raised

by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

4. This paragraph consists of Plaintiff's characterization of itself and its work. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph.
5. The first sentence of this paragraph consists of Plaintiff's characterization of itself and its work. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in the first sentence of this paragraph. Allegations in the first sentence of this paragraph also purport to characterize a website by FDA, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the website, the first sentence of this paragraph is denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information. The allegations in the second sentence of this paragraph set forth Plaintiff's conclusions of law, to which no response is required. Furthermore, the allegations in the second sentence of this paragraph purport to characterize 21 C.F.R. § 601.51(e), which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the regulation, the second sentence of this paragraph is denied.
6. Defendant admits this paragraph and avers that footnotes 5 and 6 of Plaintiff's Complaint are copied verbatim from footnotes 1 and 2 of Plaintiff's Freedom of Information Act ("FOIA") request. Defendant respectfully refers the Court to the FOIA request dated August 27, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.1.*

7. This allegations in this paragraph sets forth Plaintiff's alleged motivations for its FOIA request about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations. They do not set forth a claim for relief or aver facts in support of a claim to which a response is required. Furthermore, the allegations in this paragraph consist of Plaintiff's opinions rather than facts, as well as speculation, such that Defendant lacks sufficient information to admit or deny.
8. Admitted that Plaintiff requested expedited processing of its FOIA request. The rest of the allegations in this paragraph purport to characterize Plaintiff's FOIA request, which speaks for itself. Defendant respectfully refers the Court to the FOIA request dated August 27, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.1.*
9. Admitted that FDA denied Plaintiff's request for expedited processing. The rest of the allegations in the first sentence of this paragraph purport to characterize FDA's letter to Plaintiff, which speaks for itself. Defendant respectfully refers the Court to FDA's letter dated September 9, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.4.* The second sentence of this paragraph consists of Plaintiff's characterization of this action, to which no response is required.
10. This paragraph consists of Plaintiff's characterization of itself and its work about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
11. This paragraph consists of Plaintiff's characterization of itself about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

12. The allegations in the first sentence are admitted. The second sentence consists of Plaintiff's legal conclusions to which no response is required.
13. This paragraph consists of Plaintiff's legal conclusions regarding jurisdiction and venue, to which no response is required.
14. Admitted.
15. The allegations in this paragraph consist of Plaintiff's characterization of "an ongoing, public national debate" by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
16. This paragraph consists of Plaintiff's characterization of alleged "declar[ations]" by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
17. The allegations in this paragraph purport to characterize a news release by FDA, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the news release, this paragraph is denied.
18. The allegations in this paragraph purport to characterize a news release by FDA, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the news release, this paragraph is denied.
19. The allegations in this paragraph purport to characterize a news release by FDA, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the news release, this paragraph is denied.
20. The allegations in this paragraph purport to characterize an article by CBS News, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the article, this paragraph is denied.

21. The allegations in this paragraph purport to characterize websites by the Centers for Disease Control and Prevention, the Department of Health and Human Services, the World Health Organization, and the Washington State Department of Health, which speak for themselves, and an article by WLNS.com, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the websites and the article, this paragraph is denied.
22. The allegations in this paragraph consist of Plaintiff's characterization of alleged "questions" raised by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations. Furthermore, this paragraph consists of Plaintiff's characterization of itself and its work about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
23. Admitted that a group of individuals filed a Citizen Petition with FDA on June 1, 2021, concerning Pfizer's COVID-19 vaccine. The remaining allegations in this paragraph purport to characterize a Citizen Petition submitted to FDA and a blog post, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the Citizen Petition and the blog post, those allegations are denied.
24. The allegations in this paragraph purport to characterize three blog posts and one news article from STAT, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the blog posts and the article, this paragraph is denied.
25. The allegations in this paragraph purport to characterize a blog post, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the blog post, this paragraph is denied.

26. The allegations in this paragraph purport to characterize a biographical website, an FDA website, and a Wall Street Journal article, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the websites and the article, this paragraph is denied.
27. Denied that "FDA did not convene its advisory group, VRBPAC, to have a public meeting prior to licensure" and that "those interested were denied the opportunity to both hear discussion about the data and to offer public comment about the same." By way of further response, Defendant avers that the VRBPAC Advisory Committee held a public meeting on December 10, 2020, to discuss Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age and older. Furthermore, the allegations in this paragraph purport to characterize a letter from several senators to then-FDA Commissioner Stephen Hahn dated September 14, 2020, and an article by the Washington Times, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the letter and the article, this paragraph is denied.
28. The allegations in this paragraph purport to characterize articles by the National Law Review, Associated Press, Forbes, CNN, Yahoo! News, CNBC, CBS, ABC News, KPBS, Reuters, The Hill, University Business, NBC News, NPR, Patch, NBC New York, nj.com, Mercury News, The New York Times, Boston Herald, Mississippi Free Press, Huffington Post, The Advocate, and the Los Angeles Times, as well as websites by the White House, New York City, CVS, the University of Colorado—Boulder, the University of California—Berkeley, Harvard University, George Mason University, the University of Pittsburgh, New York State, California Department of Public Health, and

City of Denver, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the articles, this paragraph is denied. In addition, the paragraph consists of Plaintiff's characterization of alleged "objections" raised by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

29. The allegations in this paragraph purport to characterize a bill, an article by The Hill, a White House website, and an article by CNN, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the bill, articles, and website, this paragraph is denied.
30. The allegations in this paragraph purport to characterize two New York state senate bills and articles by nj.com and eastcountytoday.com, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the bills and articles, this paragraph is denied.
31. The allegations in this paragraph purport to characterize articles from USA Today, MSN.com, The New York Times, and Yahoo! News, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the articles, this paragraph is denied.
32. The allegations in this paragraph purport to characterize an article by NBC News and a video on YouTube, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the article and video, this paragraph is denied.
33. Admitted that Plaintiff submitted a FOIA request to FDA on August 27, 2021. The remaining allegations in the first sentence of this paragraph consist of Plaintiff's characterization of itself and its work. Defendant lacks knowledge or information

sufficient to form a belief about the truth of the remaining allegations in the first sentence of this paragraph. Furthermore, an allegation in the first sentence of this paragraph purports to characterize an FDA website, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the website, this allegation in the first sentence of this paragraph is denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information. Defendant admits the second sentence of this paragraph and avers that footnotes 41 and 42 of Plaintiff's Complaint are copied verbatim from footnotes 1 and 2 of Plaintiff's FOIA request. Defendant respectfully refers the Court to the FOIA request dated August 27, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.1.*

34. The allegations in this paragraph purport to characterize a FOIA Request Confirmation, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the FOIA Request Confirmation, this paragraph is denied. Defendant respectfully refers the Court to the FOIA Request Confirmation from FDA to Plaintiff dated August 27, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.2.*
35. Admitted. Defendant respectfully refers the Court to the letter from FDA to Plaintiff dated August 31, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.3.*
36. Admitted. Defendant respectfully refers the Court to the FOIA request dated August 27, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.1.*
37. Admitted that FDA denied Plaintiff's request for expedited processing on September 9, 2021. The rest of the allegations in this paragraph contain conclusions of law, to which no response is required, or purport to characterize FDA's letter to Plaintiff, which speaks

for itself. Defendant respectfully refers the Court to FDA's letter dated September 9, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.4.* To the extent that Plaintiff's allegations are inconsistent with FDA's letter dated September 9, 2021, this paragraph is denied.

38. This paragraph sets forth Plaintiff's conclusions of law, to which no response is required. The allegations in this paragraph also purport to characterize a statute, which speaks for itself. To the extent that a response is required, FDA denies the allegations in this paragraph.
39. Admitted that Plaintiff stated in its FOIA request that it was "primarily engaged in disseminating information" and that Plaintiff stated in its FOIA request there is an "urgency to inform the public concerning actual or alleged Federal Government activity." The rest of the allegations in the first sentence of this paragraph are Plaintiff's characterization of its FOIA request, to which no response is required. Defendant respectfully refers the Court to the FOIA request dated August 27, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.1.* To the extent that Plaintiff's allegations are inconsistent with the FOIA request, the first sentence of this paragraph is denied. As for the second sentence of this paragraph, admitted that FDA stated in its letter to Plaintiff dated September 9, 2021, that Plaintiff had not "demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual" and that Plaintiff had not demonstrated that "there exists an urgency to inform the public concerning actual or alleged Federal Government activity." The rest of the allegations in the second sentence of this paragraph are Plaintiff's characterization of FDA's letter to Plaintiff, to which no response is required. Defendant respectfully

refers the Court to FDA's letter dated September 9, 2021, for a full and accurate statement of its contents. *See Compl. Exh. A.4.* To the extent that Plaintiff's allegations are inconsistent with FDA's letter dated September 9, 2021, the second sentence of this paragraph is denied. The third sentence of this paragraph consists of Plaintiff's characterization of this action, to which no response is required. To the extent a response is required, the allegations are denied.

40. The first sentence of this paragraph consists of Plaintiff's characterization of this action, to which no response is required. To the extent a response is required, the allegations are denied. The second, third, fourth, and fifth sentences of this paragraph consist of Plaintiff's characterization of itself and its work. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in the second, third, fourth, and fifth sentences of this paragraph. Furthermore, the fifth sentence of this paragraph purports to characterize articles from Fox News, The BMJ, the Wall Street Journal, The Federalist, and ArcDigital, blog posts on The BMJ and Re-Check, and websites by Andrew Bostom, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the articles, the fifth sentence of this paragraph is denied. The sixth sentence of this paragraph consists of Plaintiff's characterization of this action and conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied.
41. This paragraph sets forth Plaintiff's conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied. Furthermore, the allegations in this paragraph purport to characterize a judicial opinion, which speaks

for itself. To the extent that Plaintiff's allegations are inconsistent with the judicial opinion, this paragraph is denied.

42. The first sentence of this paragraph consists of Plaintiff's characterization of this action, to which no response is required. To the extent a response is required, the allegations are denied. The second and third sentences of this paragraph consist of Plaintiffs' characterization of a regulation, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the regulation, the second and third sentences of this paragraph are denied. The fourth sentence of this paragraph consists of conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied.
43. This paragraph consists of Plaintiff's conclusions of law, to which no response is required. Furthermore, this paragraph purports to characterize FDA websites, a statute, and a regulation, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the website, statute, and regulation, this paragraph is denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information.
44. This paragraph consists of Plaintiff's characterization of this action and conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information.
45. This paragraph consists of Plaintiff's characterization of this action and conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied.

46. The allegations in this paragraph consist of Plaintiff's characterization of alleged "declar[ations]" and "questions" raised by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations. This paragraph also consists of Plaintiff's characterization of itself and its work about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
47. This paragraph consists of Plaintiff's speculation and characterization of this action, to which no response is required. To the extent a response is required, the allegations are denied.
48. This paragraph consists of Plaintiff's speculation and characterization of this action, to which no response is required. To the extent a response is required, the allegations are denied.
49. This paragraph consists of Plaintiff's characterization of this action, to which no response is required. To the extent a response is required, the allegations are denied. The paragraph also consists of Plaintiff's characterization of alleged "objections" raised by unnamed individuals about which Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations. Furthermore, the allegations in this paragraph purport to characterize articles by the National Law Review, Associated Press, Forbes, CNN, Yahoo! News, CNBC, CBS, ABC News, KPBS, Reuters, The Hill, University Business, NBC News, NPR, Patch, NBC New York, nj.com, Mercury News, The New York Times, Boston Herald, Mississippi Free Press, Huffington Post, The Advocate, and the Los Angeles Times, as well as websites by the White House, New York City, CVS, the University of Colorado—Boulder, the

University of California—Berkeley, Harvard University, George Mason University, the University of Pittsburgh, New York State, California Department of Public Health, and City of Denver, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the articles and websites, this paragraph is denied.

50. This paragraph consists of Plaintiff's characterization of this action and conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied. Furthermore, the allegations in this paragraph purport to characterize a website by the White House and an article by CNN, which speak for themselves. To the extent that Plaintiff's allegations are inconsistent with the website and article, this paragraph is denied.
51. This paragraph consists of Plaintiff's characterization of itself, its work, and its future actions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph.
52. This paragraph consists of Plaintiff's characterization of this action and conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied. By way of further response, FDA avers that it is committed to transparency while appropriately protecting confidential information.
53. This paragraph consists of Plaintiff's conclusions of law, to which no response is required. To the extent a response is required, the allegations are denied. This paragraph also purports to characterize a statute, which speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the statute, this paragraph is denied.

The remaining paragraphs of the Complaint contain Plaintiff's requested relief, to which no response is required. To the extent a response is required, Defendant denies the allegations

contained in the remaining paragraphs of the Complaint and further avers that Plaintiff is not entitled to any relief.

Defendant hereby denies all allegations in the Complaint not expressly admitted or denied.

DEFENSES

1. Some or all of the requested records or information may be exempt from disclosure, in whole or in part, under 5 U.S.C. § 552(b).
2. Plaintiff's FOIA request is improper to the extent it does not reasonably describe the records requested. 5 U.S.C. § 552(a)(3)(A).

Dated: October 18, 2021

Respectfully submitted,

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Counsel for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2021, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

/s/ Courtney D. Enlow
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